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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/522,766

02/27/2006

Daphne Atlas

29287

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67801

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05/19/2010

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EXAMINER

FINN, MEGHAN R

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

05/19/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/522,766 | Applicant(s) ATLAS ET AL. | |
| | Examiner MEGHAN FINN | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7,10,20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>5/12/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's Amendment filed March 01, 2010 has been received and entered into present application. No claims were canceled and claims 20-21 were added by applicant. Claims 20-21 are not drawn to the elected compound (compound J) and are thus withdrawn. Thus claims 1-2, 7 and 10 are pending.

Applicants' arguments, filed March 01, 2010 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 7, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas et al. (WO 98/29375) in view of Passi et al. (US 6,303,139), in further view of Delack et al. (US 2003/0113309 A1), each already of record, for the reasons set forth at pages 3-6 of previous office action dated August 28, 2009, of which reasons are herein incorporated by reference.

Applicant has not amended the claims 1-2, 7 and 10. Applicant added claims 20-21 which are drawn to the non-elected species and are withdrawn. Applicant has argued that claims 1-2, 7 and 10 are unobvious because many diseases are associated with oxidative stress. It is true that oxidative stress has been implicated in many diseases, however this does not mean that it is not important in multiple sclerosis and Passi et al. teaches that oxidative stress is **significantly involved in the pathogenesis of multiple sclerosis** (abstract, and column 1, lines 55-65) is more than just an allegation that it is associated with the disease. Furthermore, there is no reason that because oxidative stress is implicated in other diseases that it is not important in MS. The examiner is not making any assumptions about other diseases in which oxidative stress may be implicated as they are not under examination. The question is, given

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what was known in the art at the time of the invention would it have been obvious to one of ordinary skill in the art to use a compound known for treating oxidative stress (compound J, as taught by Atlas et al.) for a disease (MS) that it is known in which oxidative stress plays an important role in the pathogenesis of the disease (taught by Passi et al.) **AND** that these patients have an antioxidant deficiency (taught by Delack et al.). The examiner's opinion is that yes, it would have been obvious to use the compound J of Atlas et al. to treat multiple sclerosis and that there would have been a reasonable expectation of success given the known antioxidant deficiency and the known involvement of oxidative stress which the compound J would be expected to treat. Would this necessary eliminate all symptoms of MS? Maybe not, but that is not required because "treating" means making the situation or disease better in some aspect, not necessarily completely fixing the disease or treating all aspects. There would be motivation to give compound J to a patient with MS to combat the oxidative stress these patients are known to have and this would result in the treatment claimed.

Applicant has also argued that many compounds are known to be antioxidants but only possibly one has been shown to treat MS. Applicant cites a table but does not give any information about the source of such table – it appears to the examiner to be a listing of current approved treatments for MS that one would find on Wikipedia.org or WebMD.com. There is no reason to believe this is a comprehensive list or that it represents all the treatments known in the art, in fact it may be limited to only those which have received FDA approval already. Furthermore, the fact that others are not yet approved and known to the general public does not mean that one would expect

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that the treatment suggested by the art above would not work. Applicant keeps asserting that only 1 antioxidant could be known to treat MS and the examiner strongly disagrees with this statement. In fact applicant has also completely ignored the mention and citation of Malfroy-Camine et al. (US 6,589,948) in the previous office action which was provided to show examples of other compounds which are antioxidant compounds that were indicated for treatment of multiple sclerosis (column 4, lines 26-46). This is a whole class of anti-oxidant compounds which are shown to be useful for treatment of MS so applicant's allegations that only 1 known antioxidant is known for treatment of MS is false.

Applicant has also disagreed with the examiner over whether vitamins C and E have been shown to not treat MS. Applicant provided a reference which showed that vitamins C and E do not decrease the risk or incidence of MS in patients. The examiner pointed out that preventing and treating are not the same thing and the fact that the patients still developed MS does not mean it wouldn't treat it. Applicant argues that by showing the rate of MS was not reduced and that so many cases of MS developed while taking these vitamins that the article shows that they do not treat MS. The examiner again strongly disagrees. Treatment and preventing are two different things. Someone can take Advil or another pain reliever hoping to prevent a headache/pain from occurring. It often does not prevent the headache/pain from occurring, and often does not completely eliminate the pain but it usually does provide some measure of relief and does in fact treat the headache. The vitamins C and E may do nothing to keep someone from developing MS and at the same time could treat the MS once the

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disease is present or treat a symptom of the disease which would still be considered an effective treatment for the disease as any relief in symptoms is a positive thing.

Applicant's argument has been very carefully and fully considered however it is not deemed persuasive and thus the rejection of claims 1-2, 7 and 10 is **maintained**.

Conclusion

Rejection of claims 1-2, 7 and 10 is deemed proper and is **maintained**.

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/
Primary Examiner, Art Unit 1614